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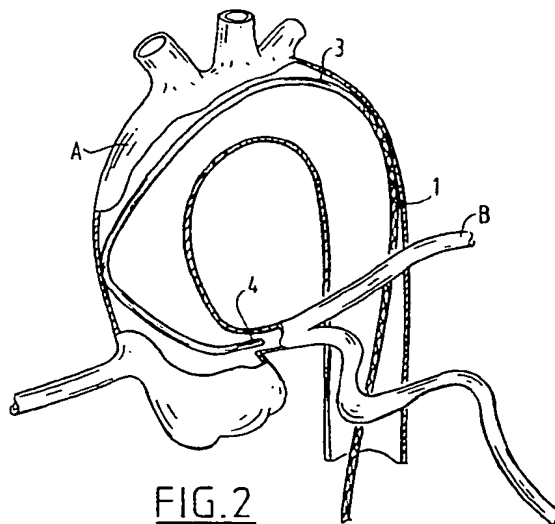
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**NL-2517 GK The Hague(NL)**(54) **Catheter for angioplasty.**

(57) Guiding catheter for angioplasty, substantially consisting of a hollow tube (1)(lumen) of flexible torsion-stiff material, onto an end (3) of which connects a tubular extension of flexible material, which is curved according to predetermined varying radii of curvature, and the free end portion (4) of which is provided with a softer material than the flexible material, wherein the end portion (4) of softer material is provided with at least three radially protruding elements (9), preferably having an arc-like outer curvature seen in tangential direction. A very great stability of the end portion (4) of softer material is herewith achieved at the transition between the aorta (A) and the blood vessel (B), e.g. the ostium irrespective of the great speed of the blood flow and reactive forces due to the introduction of the balloon catheter or any other catheter.

**FIG. 2****EP 0 454 264 A1**

The invention relates to a guiding catheter for angioplasty, substantially consisting of a hollow tube (lumen) of flexible torsion-stiff material, onto an end of which connects a tubular extension of flexible material, which is curved according to pre-determined varying radii of curvature, and the free end portion of which is provided with a softer material than the flexible material.

The known catheters of the type described in the preamble are used as guiding members during heart catheterization, wherein the relatively wide hollow tube is guided along a previously inserted wire. The tube therefore has to be both flexible and torsion-stiff in order to steer the free end in the aorta and the blood vessels connecting thereto such that the correct entrance, for instance ostium, is found. To this end the tubular extension is also curved according to predetermined radii of curvature in order to be able to reach the correct entrance of the blood vessel. The soft end portion serves to prevent damage to the wall of the aorta or the blood vessel. With the known catheters, holding the end portion in the correct position at the transition between the aorta and the blood vessel, as said ostium, remains a problem because of for instance the great speed of the blood flow and reactive forces due to the introduction of the balloon catheter or any other catheter. While it is true that the curved tubular extension is supported against the wall of the extension, the flexibility of this extension and the soft end portion nevertheless causes a continuously accurate position difficult to maintain.

The invention has for its object to obviate the above mentioned drawback and provides for that purpose a guiding catheter which is distinguished in that the end portion of softer material is provided with at least three radially protruding elements.

These three radially protruding elements ensure a a-traumatic centering of the soft end portion in the blood vessel in particular said ostium, whereby this end portion remains better in position, while due to the distance creating working the free passage of the blood is hardly or not at all obstructed. It is necessary that a continuous blood flow has to be maintained around the catheter in order to supply blood to the heart vessels.

In a preferred embodiment the radially protruding elements are embodied as ridge-shaped parts extending in axial direction of the catheter, preferably having an arc-like outer curvature seen in tangential direction. A very great stability of the end portion of softer material is herewith achieved.

According to a further development of the invention it is recommended to support the inside of the end portion of softer material by a narrowed tubular portion of the extension, whereby the lengthwise stability of the end portion is improved.

In order to further the pliability of the protruding elements or ridge-shaped parts in inward sense, it is advantageous according to the invention to embody this narrowed tubular portion of the extension with passages at the location of the protruding elements.

Due to these passages the protruding elements can be pressed inward; so insertion of the catheter through a punction sheath, according the Seldinger technique is still possible, without enlarging the inner diameter of the punction sheath.

Above mentioned and other features of the invention will be further elucidated in the figure description hereinafter of a number of embodiments. In the drawing:

Fig. 1 shows a perspective view of a patient provided with a catheter according to the invention,

fig. 2 shows a large detail of the aorta with a catheter according to the invention arranged therein,

fig. 3 and fig. 4 show respectively a lengthwise and a transverse section of the extremity of the catheter from fig. 2 according to a first embodiment,

fig. 5 shows a perspective view of the centering of the embodiment of fig. 3 in a blood vessel according to a perspective view,

fig. 6 is a detail of the wall of the end portion of the catheter from fig. 3 in a different position of the protruding element,

fig. 7 shows a perspective view, corresponding with that of fig. 5, of an alternative embodiment of the end portion of the catheter according to the invention.

The catheter shown in the figures consists of a hollow tube 1 of flexible torsion-stiff material, which at the end 3 remote from the hand grip 2 is extended with a tubular curved portion, the bends of which each display an adapted radius of curvature, see fig. 2. This curved extended portion 3 is such that it is adapted to the curvature of the aorta A, whereby it is possible to place the end portion of the extended portion 3 at the entrance of a blood vessel B connecting onto the aorta A. The curved end portion 3 is carried via an artery in the arm of the patient from fig. 1 to the aorta, by pushing it up and rotating it such that the positioning at the entrance of the blood vessel B can take place. Therein the curve of the tubular part 1 as well as that of portion 3 supports against the side wall of the aorta. This method of positioning is however still not sufficient to position the end 4, which is further elucidated hereunder, precisely in the debouchement of the blood vessel, because of the strong flow to which the blood is subjected there and/or the reactive forces of the introduced catheters.

Shown in fig. 3-6 is a first embodiment of the end portion 4 of the catheter 1 from fig. 1 and 2. The end portion is substantially formed of a sleeve-like part 5 of soft material, which gives sufficiently as the catheter is pushed through the artery, so that no damage occurs to the wall thereof. The soft material 5 is supported on the inner side by the hollow tubular portion 6 which is more narrowed in circumference at 7.

The soft material of the end portion 5 is thickened radially outward at 8 such that ridge-shaped elements 9 are created which display a determined length. The ridge-shaped, radially protruding elements 9 end at a distance from the free end of the end portion 5.

According to a feature of the invention the more narrowed portion 7 of the tubular extension piece 6 is provided with a passage opening 10 close to the radially protruding elements 9, whereby it is possible for the radially protruding element 9 to be able to give inwardly through this opening 10, should this appear to be necessary during the passage of the catheter in a blood vessel or during insertion into a puncture sheath, see fig. 6.

The above mentioned embodiment has the following result.

If the end portion with the protruding elements 9 is carried into the debouchement of the blood vessel B, see fig. 5, with a correct choice of catheter the outer periphery of the protruding elements 9 will rest against the inner wall of the blood vessel B, whereby the end portion comes to lie accurately centered in the blood vessel B. With this embodiment it is not only possible to accurately centre and position the end portion, but also to ensure the necessary through-flow of blood. The catheter can nevertheless be used for feeding all usual substances and to inject contrast fluid and such like.

Fig. 7 shows an alternative embodiment, wherein the ridge-shaped protrusions are formed by an end portion that is star-shaped in cross section and exhibits a large number of parallel ribs 11 distributed regularly over the periphery.

It is finally noted that past the passage opening 10 in fig. 3 the end portion 6 can have a ring 12 that is observable with X-rays, whereby the position of the end portion during the operation can be accurately determined.

Such a ring 12 can likewise be used with the end portion 4 in fig. 7, for which purpose this ring can either be circular or can likewise display a star-shaped form similar to the cross section of the end portion.

Other embodiments are of course possible within the scope of the invention.

The ridge-like rib 9 can for instance be subdivided into more, successive protruding elements, whereby an interrupted ridge results. This can be

an advantage for assisting the blood flow.

The narrowed part 7 can extend beyond the soft tip end, as a-traumatic insertion is still possible due to the ridges extending radially.

## Claims

1. Catheter for angioplasty, substantially consisting of a hollow tube (lumen) of flexible torsion-stiff material, onto one end of which connects a tubular extension of flexible material which is curved according to predetermined varying radii of curvature, and the free end portion of which is provided with a softer material than the flexible material, **characterized in that** said end portion of softer material is provided with at least three radially protruding elements.
2. Catheter as claimed in claim 1, **characterized in that** the or each radially protruding element is given a ridge-like form.
3. Catheter as claimed in claim 2, **characterized in that** said ridge-like element has an arc-like outer curvature seen in tangential direction.
4. Catheter as claimed in claim 1 or 3, **characterized in that** each protruding element ends at a distance from the end opening of the end portion of the catheter.
5. Catheter as claimed in any of the preceding claims, **characterized in that** the inner side of the end portion is supported by a narrowed portion of the tubular extension.
6. Catheter as claimed in claim 5, **characterized in that** the extension is provided in each case with a passage opening at the location of the radially protruding elements.
7. Catheter as claimed in any of the preceding claims, **characterized in that** an annular element observable by X-rays is embedded in the end portion, preferably between the outflow opening and the end of the radially protruding element.

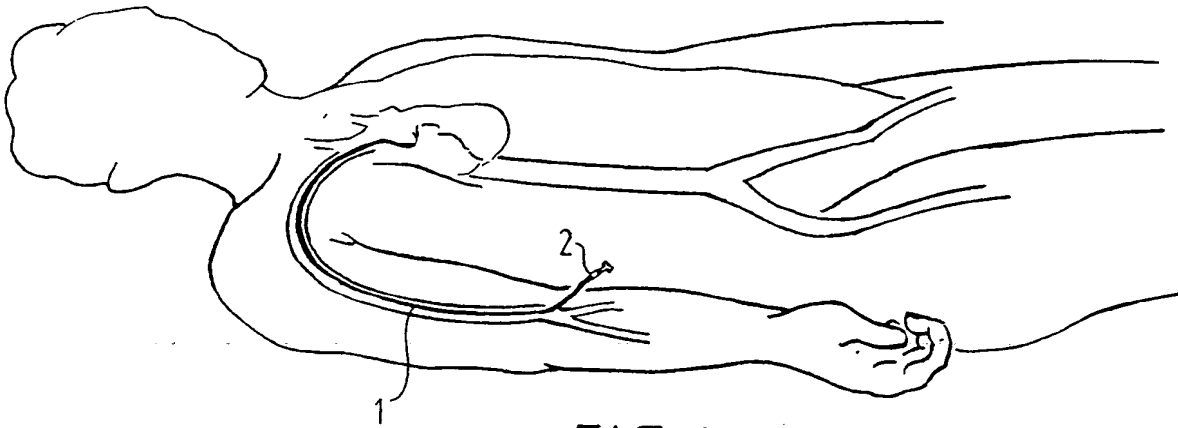


FIG.1

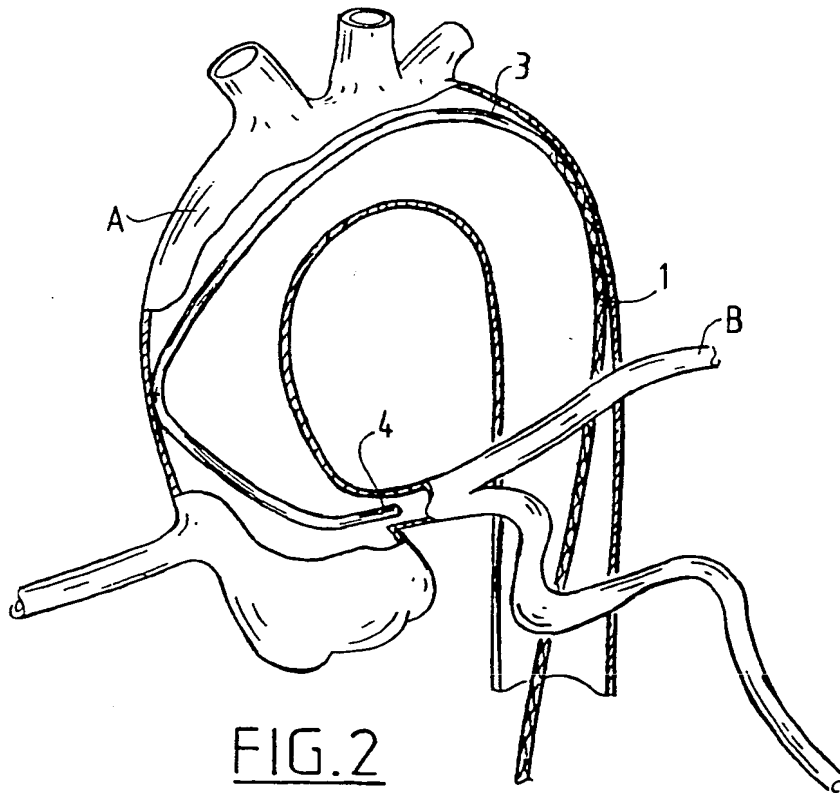
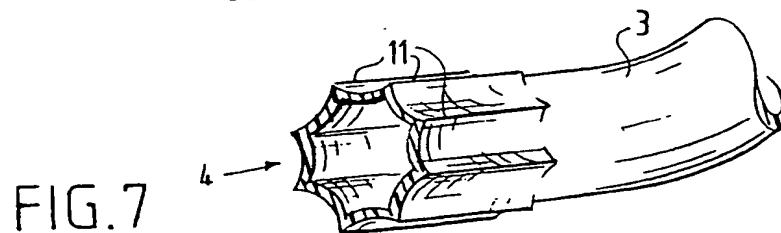
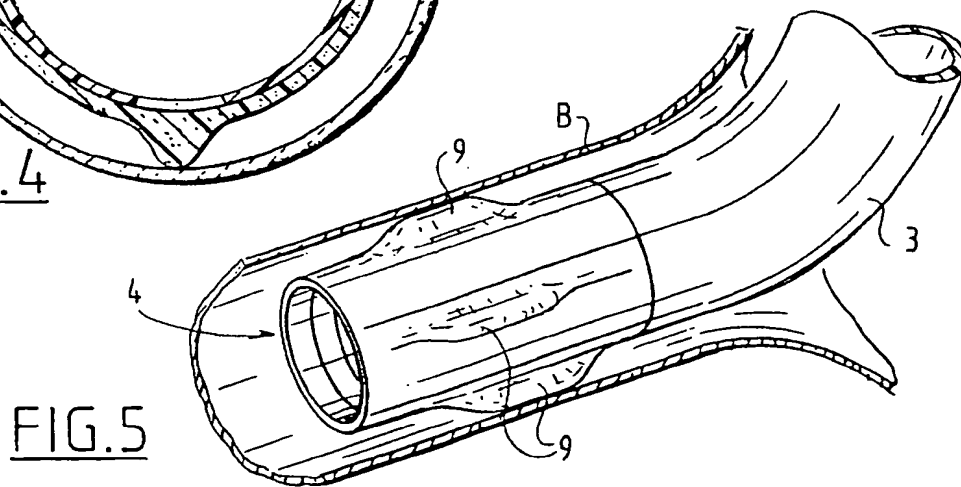
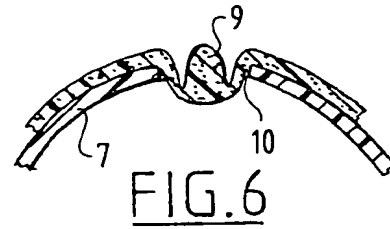
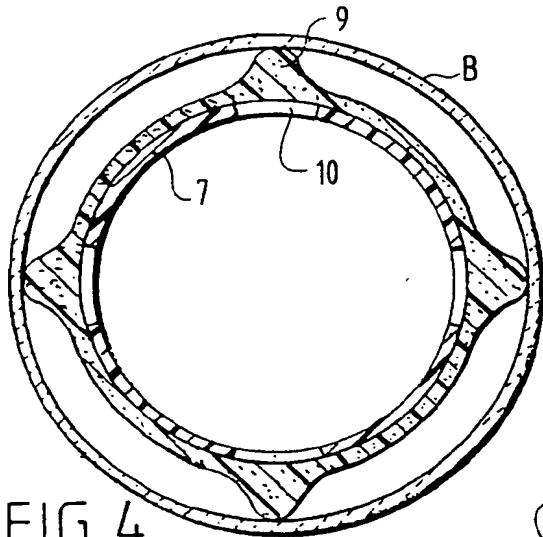
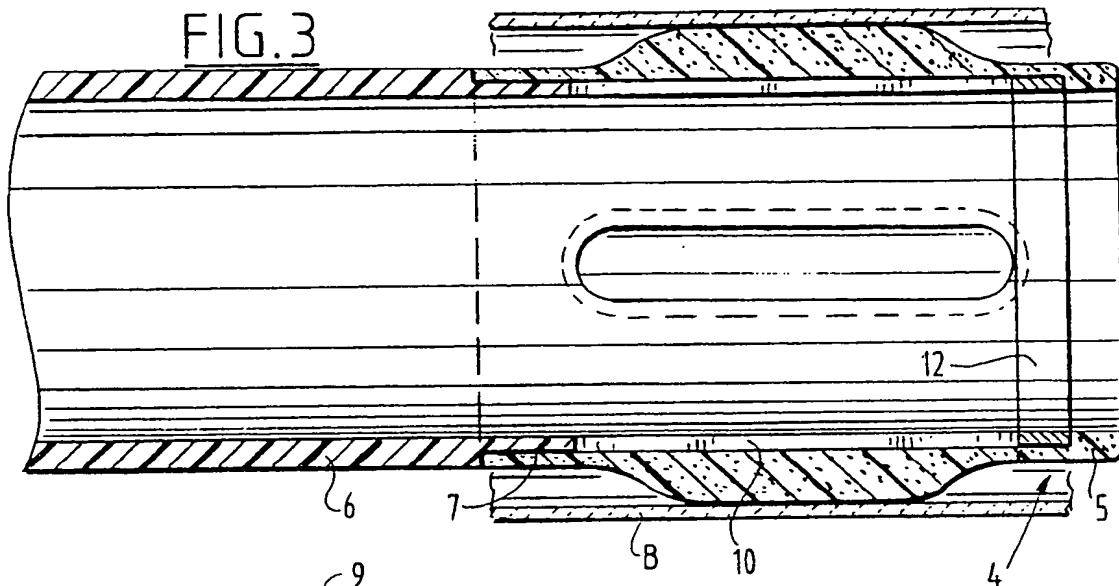


FIG.2



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## EUROPEAN SEARCH REPORT

Application Number

| DOCUMENTS CONSIDERED TO BE RELEVANT  |   |  | EP 91200984.2                                       |
|--|---|--|---|
| Category   | Citation of document with indication, where appropriate, of relevant passages   | Relevant to claim                              | CLASSIFICATION OF THE APPLICATION (Int. CL.5)       |
| A  | <u>WO - A1 - 84/01 512</u><br>(R. NISSEN)<br>* Totality; especially fig. 1,2; page 1, lines 1-16; page 3, line 25 - page 4, line 8; amended claim 1 * | 1  | A 61 M 25/00  |
| A  | <u>US - A - 4 832 028</u><br>(P.V. PATEL)<br>* Totality; especially fig. 1,2; column 2, lines 4-18, 24-27, 52-64; column 3, lines 15-27 *             | 1  |   |
| A  | <u>WO - A1 - 89/03 701</u><br>(D. HARMJANZ)<br>* Totality; especially fig. 1-6; page 1, lines 1-4; page 5, line 1 - page 6, line 8; claims 1,5 *      | 1  |   |
| A  | <u>US - A - 4 886 506</u><br>(E.M. LOVGREN et al.)<br>* Fig. 1,2; column 3, line 35 - column 5, line 8 *  | 1  | TECHNICAL FIELDS SEARCHED (Int. CL.5)<br><br>A 61 M |
| A  | <u>US - A - 4 748 984</u><br>(P.V. PATEL)<br>* Totality *   | 1  |   |
| The present search report has been drawn up for all claims   |   |  |   |
| Place of search<br>VIENNA  |   | Date of completion of the search<br>07-08-1991 | Examiner<br>LUDWIG                                  |
| <b>CATEGORY OF CITED DOCUMENTS</b><br><br>X : particularly relevant if taken alone<br>Y : particularly relevant if combined with another document of the same category<br>A : technological background<br>O : non-written disclosure<br>P : intermediate document<br><br>T : theory or principle underlying the invention<br>E : earlier patent document, but published on, or after the filing date<br>D : document cited in the application<br>L : document cited for other reasons<br>-----<br>& : member of the same patent family, corresponding document |   |  |   |

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